Noninvasive Medical Technologies, Inc.

6412 S. Arville Street
Las Vegas, NV 89118
1-888-466-8552 · 702-614-4170 (Fax)
www.nmtinc.org
www.zoefluidmonitor.org

REV 5, 2011

NMT Noninvasive Medical Technologies

ZOE® Monitor USER MANUAL

NONINVASIVE TECHNOLOGIES ACROSS THE CARE CONTINUUM

HEADQUARTERS: 6412 S. ARVILLE STREET
LAS VEGAS, NV 89118

TOLL FREE: 1-888-466-8552 · FAX: 702-614-4170
WWW.NMTINC.ORG
WWW.ZOEFLUIDMONITOR.ORG

Proper skin prep is **CRITICAL** for accurate Zo measurement.
Always prep before electrode placement!

	Consult the operator's manual for more details
	ZOE® is a Class II Medical Electrical Equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions.
	ZOE® uses Class BF applied parts

ZOE® Monitor is a prescription device to be used on or by, the order of a Doctor or licensed health care professional.

Only for use with medical grade power adapter
Model # GTM41060-1505 or
Four (4) AA Alkaline Batteries.

Noninvasive Medical Technologies, Inc.

6412 S. Arville Street
Las Vegas, NV 89118
1-888-466-8552 · 702-614-4170 (Fax)
www.nmtinc.org
www.zoefluidmonitor.org

Zo Tracking Log

DATE	TIME	Zo Value

USING ZOE®

POWER

Battery Install

- Slide open the battery door on the bottom of the ZOE® monitor.
- Insert four (4) AA Alkaline batteries as shown on the inside of the battery compartment.
- Replace the battery door.

OR

AC Power Connection

- Insert the AC Power Pack connector end into the AC power Pack, the insertion site is on the back of the ZOE monitor.
- Plug the AC Power Pack into a standard electrical outlet.

ZOE® HOOK-UP

Skin Prep (also see page 9)

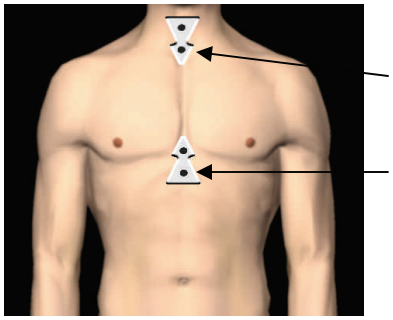
- Before placing electrodes onto the skin, make sure that the skin is clean and dry.
- All hair should be removed from the site where the electrode will be placed, so to assure a good connection to the skin.
- For best results, allow electrodes to adhere to the skin for no less than 5 minutes prior to pressing the START button.

Preparing the skin where the Electrodes will be placed

1. Look on figure X where electrodes #1 and #2 are to be placed. Be sure the patient's skin in those areas is clean and dry.
2. If those areas have a lot of hair, the area needs to be shaved or the electrodes will not adhere correctly and the Zo readings will not be accurate.

Connecting the ZOE® Cable

1. Connect the AC adapter into the ZOE® back, and plug device into an outlet, or insert batteries.
2. Snap the new electrodes to the ZOE® cable. White snap on the arrow tip and black snap on the arrow base.
3. Remove the clear backing from the electrode and place onto the skin
4. Place Electrode 1 just above the top of your breastbone with the arrow tip pointing down.
5. Place Electrode 2 just below the bottom of your breast-bone with the arrow tip pointing up.
6. Wait 5 minutes, then press the "START" button.
7. Wait, without moving or drinking, for the Zo number to appear in the ZOE® window.



CAUTION!

Only approved ZOE® electrodes should be used with the ZOE® Fluid Monitor. Zoe readings obtained from unapproved electrodes may not be accurate!

ZOE Measurement

- For best results wait 5 minutes for electrodes to seed.
- Press the "**START**" button on the front of the ZOE Monitor.
- Wait about 30 seconds sitting up straight or lying flat, without moving or drinking, for the Zo value to appear in the ZOE Display Window.
-

CAUTION

- DO NOT press the "START" button while the ZOE® Monitor is measuring the Zo value. Doing this only slows down the measurement process.
- Call your nurse or doctor if your Zo is less than 19 or greater than 30. Environmental conditions or body size may effect Zo baseline. Decreasing or rising trends in Zo readings should be noted, recorded, and shared with a health professional.

NOTES

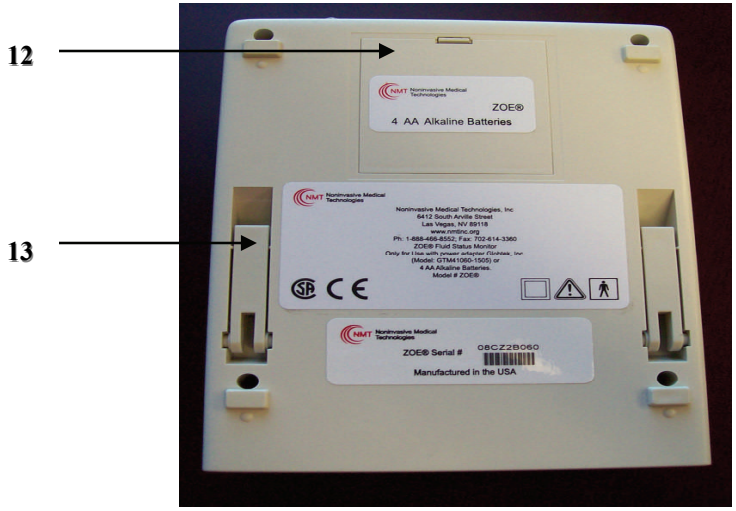
- The Zo value will automatically turn off within 30 seconds after it is displayed. Write the Zo number in your daily Zo tracking log on the back pages of this manual.
- ZOE® electrodes are for **one time use only!**

CAUTION!

- Only approved ZOE® electrodes should be used with the ZOE® Fluid Monitor. Zo readings obtained from unapproved electrodes may not be accurate!

BACK OF ZOE® MONITOR

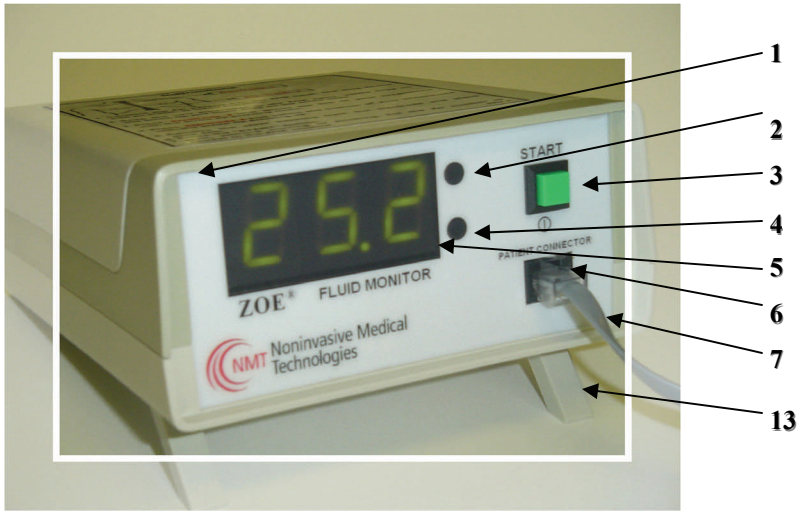
Only 5 volt ZOE® power cord should be inserted into the power supply outlet on the back of the ZOE® device.



BOTTOM OF ZOE® MONITOR

Physical Features

1. ZOE® Monitor Base
2. Cable Disconnect Indicator Light
3. **START** Button
4. Low Battery Indicator Light
5. Zo Display Window
6. ZOE® Cable Connection Site
7. ZOE® Cable
8. Power Pack
9. Power pack insertion site
10. Power Cord
11. RS232 Port
12. Battery Compartment
13. ZOE® Legs



ZOE® MONITOR BASE FRONT

CAUTION!

- Only approved ZOE® electrodes should be used with the ZOE® Fluid Monitor. Zo readings obtained from unapproved electrodes may not be accurate!

Maintenance

All services and repair on ZOE® must be conducted by an NMT Certified center. There are no user serviceable parts contained in ZOE.

Batteries

- ZOE® uses four (4) AA Alkaline batteries.
- Batteries should be checked at least once each month
- Batteries must be changed when the "low battery" light indicator is lit.
- Dispose of batteries at designated battery-disposal locations only.

Cleaning

- The outside surface of the ZOE® Monitor and the ZOE® Cable, may be cleaned with a pad soaked in alcohol (95%).

CAUTION

- Do not allow any liquid to enter the ZOE® Monitor case and avoid pouring water or other liquids onto the ZOE® Monitor base while cleaning.
- Never use abrasive tools to clean the device such as wire, steel wool or metal polish.
- During cleaning, make sure the ZOE® monitor is not exposed to temperatures above 45°C, or 113° F.

The manufacturer recommends that ZOE receive calibration check and certification annually by a NMT Certified Center.

Technical Specifications

1. Class II Medical Device

2. **Mode of Operation:**
   Intermittent Use

3. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

4. **Power:**
   5 Volts DC ZOE Medical Grade
   Power Adapter Model # GTM41060-1505
   only or four (4) AA Alkaline Batteries.

5. **Battery Life**:
   30 Tests

6. **Enclosure**:
   Flame-resistant AVS Plastic.

7. **Dimensions**: 5.82”(W) x 7.48”(L) x 2.63”(H)

8. **Weight**:
   One Pound or 2.2 Kg

9. **Measurement Current**:
   2.0 mA, 100 kHz

10. **Electrodes**:
    ZOE® Disposable Hydrogel Leads Only

11. **Operating & Storage Temperature:**
    15° - 40° C, or 41° - 113° F

12. **Relative Humidity for operation & storage**:
    20% - 80% non-condensing.

13. IP20

14. **Atmospheric Pressure:**
    50-106 kpa

Indications

ZOE® Can be used to monitor individuals with:

- Fluid management problems
- Diuretic medications
- Living with heart failure
- Living with endstage renal disease
- Recovering from coronary artery disease events.
- Suffering from, or at risk for, recurrent dehydration.

Contraindications

The ZOE® Monitor should ***not*** be used when:

- Allergies or skin sensitivities to electrode hydrogel exist.
- There is skin breakdown on chest where ZOE electrode placement is required

The ZOE® Kit

The ZOE® kit contains the following:

- ZOE® Monitor - 1
- ZOE® Cable - 1
- Electrodes – 2 sets
- AC Power pack – 1
- User Manual – 1

Introduction

The ZOE® Monitor is a transportable thoracic bioimpedance monitor that provides measurement of fluid status. Base impedance, also known as Zo, decreases when fluid increases and rises when less fluid exists in the chest. Normal thoracic Zo range is between 19-30 ohms, however every person has their own baseline Zo value. Fluid status changes should be noted and shared with professional medical clinicians when Zo readings vary from typical daily values.

The ZOE® Monitor measures fluid status and is an assessment tool, it is NOT intended to be a medical diagnostic device. This monitor can be used with adults in clinical or home settings. Collecting Zo data the same time each day provides the most accurate measure of daily fluid status changes. Measuring Zo daily also helps detect the patient's responses to drug and other interventions ordered by the physician.

The physician or designated healthcare provider is responsible for interpreting what assessment, intervention, or action is required as a result of changing Zo values.

It is recommended that Zo measurements are taken at the same time everyday!

Troubleshooting

Problem	Possible Causes	Solutions
The ZOE® Monitor displays Implausible results	Ω Low Battery Ω Inadequate connection with electrodes Ω ZOE ®cable has become disconnected	Ω Allow batteries to cool for 5 minutes then retry the Zo measurement. Ω Replace all batteries Ω Press electrodes onto clean skin Ω Check all ZOE® cable connections
No Zo results are displayed in the ZOE®window	Ω ZOE® cable has become disconnected Ω Inadequate power	Ω Check all ZOE® cable connections Ω Replace batteries Ω Plug in the AC Power Pack
The ZOE® Monitor displays LO	Ω Zo measurement is less than 15 ohms. Ω Electrodes have not had time to seed.	Ω Repeat measurement 2 more times. Ω Wait 5 minutes for electrodes to seed then re-measure.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class II & EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devises in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device (s) is connected.
- Consult the manufacturer or field service technician for help.

Zo Tracking Log

ZOE® greatest value is providing a number that is tracked over time to detect early changes in fluid status. Write in your Zo number on this tracking log every day, so you know how your Zo value today compares with yesterday. Call your nurse or doctor if your Zo is less than 19 or greater than 30.

Remember that the best results are obtained when ZOE® is used at the same time every day!

Table of Contents

Introduction 4

Indications & Contraindications 5

ZOE® Monitor Kit 5

Physical Features 6, 7

Using ZOE® Monitor 8

Power
- AC Connection 8
- Battery Install 8

Hook–up 9
- ZOE cable connect 9
- Electrode placement 9
  - Skin Prep 9
  - Snapping cable to electrode 9
- Zo Measurement 10

Maintenance 11
- Batteries 11
- Cleaning 11

Technical Specifications 12

Troubleshooting 13, 14

Zo Tracking Log 15